

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 August 2009 has been entered.

### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. France 0208467, filed on 05 July 2002 has been received.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

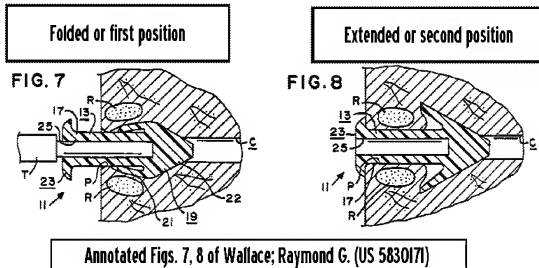
4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-7, 9, 10, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace; Raymond G. (US 5830171) in view of Zhou et al. (US 6234175) in view of Thompson; Bruce R. (US 4312612).
6. Regarding claims 1, 20 and 21, Wallace discloses a punctal occluder (col. 2, lines 29-37, col. 3, lines 50-54, Fig. 1, punctal occluder 11) adaptable for use as a meatal occluder of a human eye, comprising:
7. [1] a substantially cylindrical body (col. 3, lines 50-54 and Figs. 1-3, shank 13); and
  8. [1] at least one fin (col. 3, line 60, Figs. 1-3, wing portion 21);
  9. [1] adapted to take up a folded position wherein the fin is substantially folded into a reduced diameter portion of the cylindrical body (col. 3, lines 55-64, especially lines 60-61 and Fig. 7, wing portion 21 having a first collapsed position, see annotated figure below); and
  10. [1] an extended position wherein the fin projects from the cylindrical body (col. 3, lines 64-67, especially lines 64-65 and Fig. 8, wing portion 21 having second expanded position, see annotated figure below);
  11. [1] wherein said fin comprises a heat-deformable material (col. 5, lines 8-13 silicone); and

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12. [1] wherein the fin comprises a free end (col. 4, lines 22-24, Figs. 6-8, wing portion 21 optionally comprising individual wing elements, and depicted as having a free end opposite nose portion 22).

13. [1, 21] Examiner notes that Wallace uses the same material, silicone (col. 5, lines 8-13) as disclosed in the immediate specification (p. 8, lines 1-5, especially line 2), therefore the material used by Wallace is fully capable of being heat-deformable as claimed [claim 1].



14. Wallace discloses the invention substantially as claimed, see above. However, Wallace is silent whether body heat moves the fin, and lacks free ends housed in a reduced diameter portion as claimed [1, 20]. Additionally, Wallace is silent regarding the temperature at which the silicon material deforms as claimed [21]. Instead, Wallace discloses that wing portion 21 deforms from mechanical forces when manipulating occluder 11 between closed, opened and reversed positions (cols. 4-5, lines 56-4).

15. Zhou discloses an ocular plug comprising a fin and being made of materials that adapt to an individual's punctum or canaliculus through material properties (col. 1, lines 11-19, especially lines 15-19). [1] Here, Zhou selects a silicon material to form a fin that expands upon exposure to a heating effect of a human body (col. 3, lines 39-44, especially line 43, silicone elastomers; col. 8, lines 25-43, especially lines 14-18, 39-43, smart plug comprising silicone elastomers and adapting to size of ocular channel; Figs. 2, 8). [21] Additionally, Zhou discloses materials that change in response to a temperature near body temperature (col. 7, lines 14-23, materials with  $T_m$  less than about 37 degrees C).

16. Zhou provides the advantage of more closely matching an individuals' physiology to prevent an ocular plug from being dislodged during use. One would have been motivated to modify Wallace with the specific shape-changing silicone elastomer of Zhou, since Wallace calls for a material that returns to an original shape after deformation (col. 5, lines 4-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wallace as discussed with the shape-changing silicone elastomer of Zhou in order to change the shape of an ocular plug during an implanting step.

17. Wallace and Zhou disclose the invention substantially as claimed, see above. However, Wallace and Zhou lack free ends housed in a reduced diameter portion as claimed [1, 20]. Thompson discloses a screw fixing device and plug for insertion in an aperture (col. 1, lines 5-11, col. 2, lines 28-33, Figs. 1-6, screw fixing device) further comprising:

18. [1] a free end substantially housed into a reduced diameter portion of a cylindrical body, when the fin is in a folded position (col. 2, lines 42-55. especially lines 46-49, Fig. 4, wings 6 folding into recesses near tapered surfaces 8);

19. [20] wherein when the fin is in the folded position the fin is substantially folded into a reduced diameter portion of the cylindrical body so as to preserve the cylindrical shape of the cylindrical body (Fig. 4, folded wings 6 preserving cylindrical shape of cylindrical body).

20. Thompson reduces the diameter of a fixation device inserted into an aperture (col. 1, lines 30-44, especially lines 57-62, wings displaced inwardly when inserting device into aperture). Both Wallace and Thompson anchor a cylindrical fixing device into an aperture with expanding fins. While Thompson fixes panels together and is not implanted in living tissue, a person having ordinary skill in the art would reasonably expect similar results from a fixing device having a reduced diameter portion. That is, reducing the diameter of a fixing device eases insertion. Wallace calls for an implant that is easy to insert (col. 6, lines 5-9, especially line 7). Therefore, one would have been motivated to modify Wallace and Zhou with the reduced diameter portions of Thompson.

21. Regarding claims 2 and 3, Wallace discloses a meatal occluder characterized in that it is made from silicone (col. 5, lines 8-13). Examiner notes that silicone is a heat-expandable material, since it is capable of expanding when heated. In other words, the language "heat-expandable" is being interpreted to include materials that expand when heated, such as silicone. Additionally, Applicant discloses silicone as a suitable heat-

expandable material for forming the implant (immediate specification, p. 7-8, lines 35-5, especially line 2 and lines 11-15, especially line 13, "silicones"). Therefore, Examiner interprets the silicone material of Wallace as anticipating the claimed heat-expandable material.

22. Regarding claim 4, Wallace discloses the invention as substantially claimed, including silicone as discussed above. The specification of the immediate application discloses silicone as a polymer capable of having a vitreous transition temperature from -10°C to 30° (p. 8, lines 11-15). Therefore, the property of vitreous transition temperature is an intrinsic property of the materials used, and the device of Wallace is capable of having a vitreous transition temperature from -10°C to 30°C. Additionally, Zhou discloses materials with T<sub>m</sub> less than about 37 degrees C (col. 7, lines 14-23).

23. Regarding claim 5, Wallace discloses a meatal occluder characterized in that said fin pivots between said folded position and said extended position about an axis perpendicular to a longitudinal plane of said meatal occluder (col. 4, lines 35-42 and Figs. 7 and 9, wing portion 21 pivoting about axis perpendicular to longitudinal plane of shank 13).

24. Regarding claim 6, Wallace depicts a meatal occluder characterized in that said fin when in said folded position extends in a direction substantially parallel to the longitudinal direction of the cylindrical body (Fig. 7, wing portion 21 extending substantially parallel to shank 13).

25. Regarding claim 7, Wallace depicts a meatal occluder characterized in that said fin is situated in the vicinity of one end of said cylindrical body, a free end of said fin,

when in the folded position, extending in the direction of the opposite end of said cylindrical body (Fig. 9, end of wing portion 21 having folded position extending in direction opposite of shank 13).

26. Regarding claim 9, Wallace discloses a meatal occluder characterized in that said fin is situated in the vicinity of a tapered end of said cylindrical body, the opposite end of said cylindrical body comprising a flange (column 4, lines 22-24 and 43-49; Figs. 2 and 3, flange 23 near nose portion 22).

27. Regarding claim 10, Wallace discloses a meatal occluder characterized in that it comprises a plurality of fins regularly distributed on the cylindrical body of said occluder (col. 4, lines 22-24, "wing portion 21 may be formed by a plurality of individual wing elements").

28. Claims 11-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace; Raymond G. (US 5830171) in view of Zhou et al. (US 6234175) in view of Hirohata; Toshio (US 4668145).

29. Regarding claims 11, 17 and 22, Wallace discloses a punctal occluder (col. 2, lines 29-37), adaptable for use as a meatal occluder of a human eye, as discussed for claims 1, 20 and 21 above. In the new grounds of rejection, Examiner cites Zhou as teaching a material capable of forming a fin that extends in a first position when an occluder is at room temperature, and exposure to a heating effect of a human body causes the at least one fin to move from the first position to a second position. Zhou also teaches a material that changes shape below 37 degrees C. Wallace and Zhou

disclose the invention as substantially claimed; however, Wallace and Zhou lack a fin extending from the cylindrical body substantially parallel to the longitudinal axis, and positioned to extend and pivot as claimed [11, 17].

30. Hirohata discloses a fastener for coupling panels (col. 1, lines 5-11, (col. 2, lines 56-63, Figs. 2-5, female member 2); further comprising:

31. [11] a substantially cylindrical body having a longitudinal axis (col. 2, lines 56-63, Figs. 2-5, locking body portion 6);

32. [11] at least one fin (col. 2, lines 56-63, Figs. 2-5, locking pawl portions 7);

33. [11] the at least one fin having a first position in which the at least one fin extends from the cylindrical body substantially parallel to the longitudinal axis (col. 3, lines 37-46, especially lines 45-46, Figs. 4, 5, locking pawl portions 7 folded inside recesses 13);

34. [11, 17] wherein the fin moves and pivots from the first position of being arranged substantially parallel to the longitudinal axis to a second position in which the at least one fin extends outward from the longitudinal axis (col. 3, lines 45-46, Figs. 4, 5, locking pawl portions 7 flexed out of recesses 13);

35. [11] wherein when the at least one fin is in the first position, an exterior of the fin is arranged so as to preserve the cylindrical shape of the cylindrical body (Figs. 4, 5, locking pawl portions folding inside diameter of locking body portion 6); and

36. [11] wherein the fin comprises a free end (col. 3, lines 37-46, Figs. 4, 5, locking pawl portions 7 having free ends near arcuate edge 12);



37. [11] said free end being substantially housed into a reduced diameter portion of the cylindrical body, when the fin is in said first position (col. 3, lines 52-62, locking pawl portions 7 inwardly flexed into recesses 13);

38. Hirohata eases the insertion of a cylindrical fastening member (col. 5, lines 19-28, especially lines 23-24, recesses enhancing insertion property). One would be motivated to modify Wallace and Zhou with the recessed portions of Hirohata to improve an insertion property since Wallace calls for an easily inserted implant as discussed for claims 1, 20 and 21 above. Here also, Hirohata applies to the problem of fixing a cylindrical body within an aperture using flexing fins or wings.

39. Regarding claims 12, 13, 14, 15, 16, 18 and 19, see discussion of claims 2, 3, 4, 5, 7, 9 and 10 above, respectively.

40. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US 5830171) in view of Zhou et al. (US 6234175) in view of Thompson; Bruce R. (US 4312612), further in view of Hirohata; Toshio (US 4668145).

41. Regarding claim 8, Wallace, Zhou and Thompson disclose the invention as substantially claimed; see discussion of claims 1, 20 and 21 above. However, Wallace, Zhou and Thompson lack a fin pivoting between a folded position and an extended position about an axis parallel to the longitudinal direction of a cylindrical body as claimed [8]. Hirohata discloses fins that pivot about an axis parallel to the longitudinal direction of a cylindrical body, as discussed for claims 11 and 17 above. See discussion

of claims 11, 17 and 22 above regarding rationale and motivation to modify Wallace, Zhou and Thompson in view of Hirohata.

### ***Response to Arguments***

42. Applicant's arguments, see p. 9-12 filed 02 August 2009 with respect to the rejection(s) of claim(s) 1-20 under 35 USC § 103 over Wallace, Thompson and Hirohata have been fully considered and are persuasive. Therefore, the rejection is withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Wallace, Zhou, Thompson and Hirohata.

43. Applicant has amended claim 11 with the language ". . . when the fin is in said first position. . ." to provide proper antecedent basis. Therefore the objection applied 02 July 2009 is withdrawn.

44. Applicant contends that Wallace and Thompson fail to teach all the limitations of claim 1, namely an occluder that retains itself in this first/folded position. Applicant reasons that Wallace needs something external to the occluder to maintain a first/folded position such as an insertion or shipping tube. Applicant notes that Wallace and Thompson lack a cause/effect relationship between temperature and position. Examiner acknowledges that Wallace is silent whether heat deforms the occluder, and cites Zhou as teaching a material for forming an occluder that will maintain a first/folded position.

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45. New claims 21 and 22 more specifically recite that the heat-deformable material assumes the folded position when the occluder is at a temperature below 37 degrees C. Examiner cites Zhou as teaching a material with  $T_m$  less than about 37 degrees C in the new grounds of rejection.

***Conclusion***

46. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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|---------------------------|----------------|
| ◆ Zhou, Stephen Q. et al. | US 20030033015 |
| ◆ Gharib, Morteza et al.  | US 20020165478 |
| ◆ Gharib; Morteza et al.  | US 6666841     |
| ◆ Vanderbilt; David P.    | US 5217491     |

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich  
Tel (571)272-2590  
Fax 571-273-2590

48. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

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49. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

50. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Examiner, Art Unit 3761

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
8 January 2010